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## Re-evaluation of propane-1,2-diol esters of fatty acids (E 477) as a food additive

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### Abstract

The EFSA Panel on Food Additives and Flavourings (FAF) provides a scientific opinion re-evaluating the safety of propane-1,2-diol esters of fatty acids (E 477) when used as a food additive. The Scientific Committee on Food (SCF) in 1978 endorsed the acceptable daily intake (ADI) of 25 mg/kg body weight (bw) per day, expressed as propane-1,2-diol, established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974. No adverse effects were observed in short-term studies in rats and dogs at the highest doses tested. The Panel considered that E 477 did not raise a concern for genotoxicity. No chronic toxicity, carcinogenicity, reproductive and developmental toxicity studies with propane-1,2-diol esters of fatty acids were available to the Panel. The Panel considered that any potential adverse effect of propane-1,2-diol ester of fatty acids would be due to propane-1,2-diol, previously re-evaluated as a food additive and for which an ADI of 25 mg/kg bw per day was established. Considering the overall metabolic and toxicity database, the Panel confirmed the previously established ADI for propane-1,2-diol esters of fatty acids (E 477) of 25 mg/kg bw per day expressed as propane 1,2 diol. This corresponds to an ADI for E 477 of 80 mg/kg bw per day, based on the concentration of free and bound propane-1,2-diol amounting to a maximum of 31% as laid down in the EU specification. The Panel concluded that there would not be a safety concern at the reported use levels for E 477 because exposure estimates from the refined non-brand loyal scenario did not exceed the ADI for E 477 in any of the population groups. However, the Panel aims to explore the feasibility of establishing a group ADI for those food additives that result in an exposure to propane-1,2-diol, such as E 477, E 1520 and E 405. Additionally, the Panel will also consider performing a combined exposure assessment to propane-1,2-diol resulting from the use of these food additives. The Panel also recommended some modifications of the EU specifications for E 477.

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## Summary

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated propane-1,2-diol esters of fatty acids in 1974 and stated that there is evidence for hydrolysis of propane-1,2-diol esters of fatty acids resulting in the products propane-1,2-diol, for which an acceptable daily intake (ADI) of 25 mg/kg body weight (bw) per day has previously established, and fatty acids. JECFA established an ADI of 25 mg/kg bw per day for propane-1,2-diol esters of fatty acids, this ADI was expressed as propane-1,2-diol.

The Scientific Committee on Food (SCF) in 1978 endorsed the ADI of 25 mg/kg bw per day established by JECFA in 1974 for propane-1,2-diol esters of fatty acids containing less than 0.5% of the dimer or trimer of propane-1,2-diol. In 1985, the Committee was informed that the use of propane-1,2-diol esters of fatty acids with a content of dimer and trimer of propane-1,2-diol of > 0.5%, for which a temporary use has been accepted in 1978, was phased out. This maximal content of dimer and trimer is also reflected in the present EU specifications for propane-1,2-diol esters of fatty acids (E 477)

The safety of propane-1,2-diol and specific fatty acids has recently been assessed in the opinions on the re-evaluation of propane-1,2-diol (E 1520) (EFSA ANS Panel, 2018a) and of fatty acids (E 570) (EFSA ANS Panel, 2017b). No adverse effects of specific fatty acids were identified in studies reported in the EFSA opinion and an ADI of 25 mg/kg bw per day was established for propane-1,2-diol (E 1520).

*In vitro* experiments showed incomplete hydrolysis of propane-1,2-diol esters of stearate. In *in vivo* studies, the presence of propane-1,2-diol distearate in the lymph has been demonstrated.

The Panel considered that the acute toxicity of propane-1,2-diol esters of fatty acids was low.

In a 13-week study in rats with propane-1,2-diol monostearate, a no observed adverse effect level (NOAEL) of 6,768 mg/kg bw per day, the highest dose tested, was identified. In addition, no treatment-related effects were observed when propane-1,2-diol monostearate was fed to rats for 90 days at the highest dose tested (1,560 mg/kg bw per day). In dogs, no treatment-related effects were observed after feeding 432 mg propane-1,2-diol monostearate/kg bw per day, the highest dose tested.

Based on the available *in vitro* tests of limited reliability performed with propane-1,2-diol esters of fatty acids that did not show indications for a genotoxic potential and taking into account that propane-1,2-diol did not raise a concern with respect to genotoxicity, the Panel considered that the fatty acid esters of propane-1,2-diol (E 477) did not raise a concern for genotoxicity.

No chronic toxicity, carcinogenicity, reproductive and developmental toxicity studies with propane-1,2-diol esters of fatty acids were available to the Panel.

The Panel considered that any potential adverse effect of propane-1,2-diol ester of fatty acids would be due to propane-1,2-diol. Therefore, the ADI of the food additive E 477 was determined by the amount of free propane-1,2-diol and the propane-1,2-diol released from the food additive after hydrolysis. According to the EU specification, the concentration of free and bound propane-1,2-diol amounts to a maximum of 31% on a weight basis. On the worst-case assumption that 100% of propane-1,2-diol (free and bound) would be systemically available and considering the ADI for propane-1,2-diol of 25 mg/kg bw per day, this corresponds to an ADI of 80 mg/kg bw per day for propane-1,2-diol ester of fatty acids.

Propane-1,2-diol esters of fatty acids (E 477) is authorised in 13 food categories according to Annex II to Regulation (EC) No 1333/2008. Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive according to Annex II was calculated for different exposure scenarios based on maximum permitted levels (MPLs) and the reported use levels by industry. Use levels were reported from food industry for only three food categories out of the 13 in which the additive is authorised. The Panel noted that 63 (71%) out of the 92 reported use levels were related to the use of propane-1,2-diol esters of fatty acids (E 477) in edible ices (FC 03) and this was in line with the information from the Mintel's Global New Products Database (GNPD), as the main subcategories labelled with the additive were ice-creams.

The Panel considered that for the main food category (fine bakery wares) contributing to the exposure estimates, brand-loyalty would not be expected and therefore selected the refined non-brand loyal scenario as the most relevant exposure scenario for its safety evaluation. Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) via this exposure scenario was up to 6.7 mg/kg bw per day at the mean level in children and up to 16.7 mg/kg bw per day at the high (P95) level in children. Overall, it was considered that the exposure was most likely overestimated.

The Panel noted that propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) would add to the exposure to the food additive propane-1,2-diol (E 1520) and propane-1,2-diol

alginate (E 405) previously re-evaluated by EFSA. Propane-1,2-diol may be released from propane-1,2-diol esters of fatty acids (E 477) at a maximum of 31% according to the EU specifications. Based on this, and considering the highest P95 exposure level observed, the highest exposure to propane-1,2-diol was calculated to be, in the *non-brand-loyal scenario*, 5.2 mg/kg bw propane 1,2 diol per day in infants (released from 16.7 mg/kg bw per day of propane-1,2-diol esters of fatty acids (E 477)).

Considering the overall metabolic and toxicity database, the Panel confirmed the previously established ADI for propane-1,2-diol esters of fatty acids (E 477) of 25 mg/kg bw per day expressed as propane 1,2 diol. This corresponds to an ADI for propane-1,2-diol esters of fatty acids (E 477) of 80 mg/kg bw per day, based on the concentration of free and bound propane-1,2-diol amounting to a maximum of 31% as laid down in the EU specification.

The Panel concluded that there would be no safety concern at the reported use levels for propane-1,2-diol esters of fatty acids (E 477) as a food additive since the exposure estimates from the refined non-brand loyal scenario did not exceed the ADI of E 477 in any of the population groups. The Panel however noted that propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) would give rise to an increased exposure to propane-1,2-diol resulting from the use of food additives propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E 405) previously re-evaluated by the Panel (EFSA ANS Panel, 2018b). Therefore, the Panel aims to explore the feasibility of establishing a group ADI for those food additives that result in an exposure to propane-1,2-diol, such as propane-1,2-diol esters of fatty acids (E 477), propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E 405). The Panel will also consider performing a combined exposure assessment to propane-1,2-diol resulting from the use of these food additives.

The Panel recommended that the European Commission considers:

- 1) lowering the current limits for toxic elements (arsenic, lead, mercury and cadmium) in the EU specifications propane-1,2-diol esters of fatty acids (E 477) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- 2) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for *trans*-fatty acids, since propane-1,2-diol esters of fatty acids (E 477) can be manufactured by transesterification of hydrogenated fats and/or oils, which contain significant amounts of *trans*-fatty acids.
- 3) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for glycidyl esters/glycidol and 3-MCPD esters, because it is likely that residues of those substances occur in the food additive propane-1,2-diol esters of fatty acids (E 477), if they were present in the raw materials used in the manufacturing of the food additive by transesterification.
- 4) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for erucic acid since erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of propane-1,2-diol esters of fatty acids (E 477).

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## 1. Introduction

The present opinion document deals with the re-evaluation of propane-1,2-diol esters of fatty acids (E 477) when used as a food additive.

The Panel noted that propane-1,2-diol is the food additive E 1520 and is also released from the food additive propane-1,2-diol alginate (E405).

### 1.1. Background and Terms of Reference as provided by the European Commission

#### 1.1.1. Background

Regulation (EC) No 1333/2008<sup>1</sup> of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010<sup>2</sup>. This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU<sup>3</sup> of 2001. The report "Food additives in Europe 2000"<sup>4</sup> submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

#### 1.1.2. Terms of Reference

The Commission asks EFSA to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

## 1.2. Information on existing authorisations and evaluations

Propane-1,2-diol esters of fatty acids (E 477) is an authorised food additive in the European Union (EU) according to Annex II of Regulation (EC) No 1333/2008 and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012<sup>5</sup>.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated propane-1,2-diol esters of fatty acids in 1974 (JECFA, 1974b). JECFA stated that there is evidence for hydrolysis of propane-

<sup>1</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008.

<sup>2</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

<sup>3</sup> COM(2001) 542 final.

<sup>4</sup> Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord, 2002, 560.

<sup>5</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

1,2-diol esters of fatty acids resulting in the products propane-1,2-diol and fatty acids. JECFA established an acceptable daily intake (ADI) of 25 mg/kg body weight (bw) per day expressed as propane-1,2-diol for propane-1,2-diol esters of fatty acids and propane-1,2-diol (JECFA, 1974a).

The SCF endorsed the ADI of 25 mg/kg bw established by JECFA in 1974 for propane-1,2-diol esters of fatty acids containing less than 0.5% of the dimer or trimer of propane-1,2-diol (SCF, 1978). In 1985, the Committee was informed that the use of propane-1,2-diol esters of fatty acids with a content of dimer and trimer of propane-1,2-diol of > 0.5%, for which a temporary use has been accepted in 1978, was phased out (SCF, 1985). This maximal content of dimer and trimer is also reflected in the present EU specifications for propane-1,2-diol esters of fatty acids (E 477).

In 2018, the EFSA Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) performed a re-evaluation of propane-1,2-diol and derived an ADI of 25 mg/kg bw per day based on a chronic toxicity study in rats in which a no observed adverse effect level (NOAEL) of 2,500 mg/kg bw per day was identified and using a safety factor of 100 (EFSA ANS Panel, 2018a). The EFSA ANS Panel also re-evaluated propane-1,2-diol alginate (E 405) and confirmed the previously established ADI for propane-1,2-diol alginate (E 405) of 25 mg/kg bw per day expressed as propane-1,2-diol. This corresponds to an ADI for propane-1,2-diol alginate (E 405) of 55 mg/kg bw per day, based on the concentration of free and bound propane-1,2-diol amounting to a maximum of 45% (EFSA ANS Panel, 2018b).

Propane-1,2-diol esters of fatty acids was also evaluated by the Nordic Council of Ministers (TemaNord, 2002). The authors concluded that the toxicological data base did "not include what normally is required" for the allocation of an ADI and that the JECFA evaluation (JECFA, 1974b) was based primarily on the hydrolysis of propane-1,2-diol esters of fatty acids into fatty acids and propane-1,2-diol. The authors stated that the biological fate of these constituents is known and there is no need for further data.

## 2. Data and methodologies

### 2.1. Data

The Panel was not provided with a newly submitted dossier. EFSA launched public calls for data<sup>6,7,8</sup> to collect relevant information from interested parties.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to September 2018. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based, however not always these were available to the Panel.

Food consumption data from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database<sup>9</sup>) was used to estimate the dietary exposure to propane-1,2-diol esters of fatty acids (E 477).

The Mintel's Global New Products Database (GNPD) was checked to identify the use of propane-1,2-diol esters of fatty acids (E 477) in food products. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

### 2.2. Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidances from the EFSA Scientific Committee.

The ANS Panel assessed the safety of propane-1,2-diol esters of fatty acids (E 477) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and the relevant guidance documents: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001).

When the test substance was administered in the feed or in the drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption,

<sup>6</sup> Call for scientific data on miscellaneous food additives permitted in EU and belonging to several functional classes. Published: 6 July 2012. Available online: <http://www.efsa.europa.eu/sites/default/files/consultation/120706a.pdf>

<sup>7</sup> Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (batch 4). Published 12 October 2015. Available online: <http://www.efsa.europa.eu/en/data/call/151012>

<sup>8</sup> Call for technical data on salts of fatty acids (E470a,b) and related food additives authorised in the EU. Published: 19 January 2016. Available online: <http://www.efsa.europa.eu/sites/default/files/consultation/160119.pdf>

<sup>9</sup> Available online: <http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm>



the daily intake was calculated by the Panel using the relevant default values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) for studies in rodents or, in the case of other animal species, by JECFA (2000). In these cases, the daily intake is expressed as 'equivalent'.

Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive Database with the reported use levels submitted to EFSA following a call for data. Different scenarios were used to calculate exposure (see Section 3.3.1). Uncertainties on the exposure assessment were identified and discussed.

### 3. Assessment

#### 3.1. Technical data

##### 3.1.1. Identity of the substance

According to Commission Regulation (EU) No 231/2012, propane-1,2-diol esters of fatty acids (E 477) used as a food additive is identified as follows:

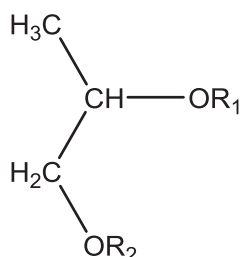
Synonyms: propylene glycol esters of fatty acids.

Definition: consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent.

Description: clear liquids or waxy white flakes, beads or solids having a bland odour.

No EINECS number has been assigned in the Commission Regulation (EU) No 231/2012 for this food additive in general.

A general structural formula is given in Figure 1.



**Figure 1:** Structural formula of propane-1,2-diol esters of fatty acids (E 477), where one R1 or R2 represent a fatty acid as acyl moiety and the remainder may represent also a fatty acid as acyl moiety or hydrogen (EFEMA, 2009 (Documentation provided to EFSA n. 2))

Propane-1,2-diol esters of fatty acids (E 477) is typically dispersible in hot water, but not in cold water and is soluble in edible oils and fats (EFEMA, 2009 (Documentation provided to EFSA n. 2)). According to the JECFA specifications, propane-1,2-diol esters of fatty acids are insoluble in water (JECFA, 2006).

Commercial, distilled propane-1,2-diol esters of fatty acids (E 477) with a minimum monoester content (90%) are mixtures of positional isomers of the monoester and propane-1,2-diol diesters and have mainly a mixed fatty acid profile. The typical fatty acid composition of distilled propane-1,2-diol esters is a blend of palmitic and stearic acid, which may vary from 60:40 to 30:70 in the C16:C18 ratio (Sparsø, 2015).

Propane-1,2-diol esters of fatty acids (E 477) is also known by the synonyms: propylene glycol esters, propylene glycol mono- and diesters, (EFEMA, 2009 (Documentation provided to EFSA n. 2)).

##### 3.1.2. Specifications

The specifications for propane-1,2-diol esters of fatty acids (E 477) as defined in the Commission Regulation (EU) No 231/2012 and by JECFA (2006) are listed in Table 1.

**Table 1:** Specifications for propane-1,2-diol esters of fatty acids (E 477) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	<b>Commission Regulation (EU) No 231/2012</b>	<b>JECFA (2006)</b>
<b>Definition</b>	Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent	Propylene glycol esters of fatty acids are mixtures of propylene glycol mono- and diesters of saturated and unsaturated fatty acids derived from edible oils and fats. The products are produced either by direct esterification of propylene glycol with fatty acids or by transesterification of propylene glycol with oils or fats. When prepared by transesterification, the product may contain residual mono- and diglycerides and glycerol. The process may be followed by molecular distillation to separate the monoesters
Assay	Content of total fatty acid ester not less than 85%	Not less than 85% total fatty acid esters
<b>Description</b>	Clear liquids or waxy white flakes, beads or solids having a bland odour	White or cream coloured solids of waxy appearance, plastic products or viscous liquids
<b>Identification</b>		
Test for propylene glycol	Passes test	Positive Glycerol may also be detectable by TLC
Test for fatty acids	Passes test	Positive
Solubility	–	Insoluble in water, soluble in ethanol and ethyl acetate
<b>Purity</b>		
Sulfated ash	Not more than 0.5% (800 ± 25°C)	Not more than 0.5%
Acids other than fatty acids	Less than 1%	Acids other than fatty acids shall not be detectable
Free fatty acids	Not more than 6% estimated as oleic acid	–
Total propane-1,2-diol	Not less than 11% and not more than 31%	Not less than 11% (soap free)
Free propane-1,2-diol	Not more than 5%	Not more than 1.5% (soap free)
Dimer and trimer of propylene glycol	Not more than 0.5%	Not more than 0.5%
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–
Cadmium	Not more than 1 mg/kg	–
Acid value	–	Not more than 4
Soap	–	Not more than 7% (as potassium stearate)

TLC: thin-layer chromatography.

According to Commission Regulation (EU) No 231/2012, purity criteria apply to the food additive free of sodium, potassium and calcium salts of fatty acids; however, these substances may be present up to a maximum level of 6% (expressed as sodium oleate).

The Panel noted that, according to the EU specifications for propane-1,2-diol esters of fatty acids (E 477), impurities of the toxic elements arsenic, lead, cadmium and mercury are accepted up to concentrations of 3, 2, 1 and 1 mg/kg, respectively. Contamination at these levels could have a significant impact on exposure to these toxic elements, which are already close to the health based guidance values or benchmark doses (lower confidence limits) established by EFSA (EFSA CONTAM Panel, 2009a,b, 2010, 2012a,b,c, 2014).

The Panel noted that, in contrast to the JECFA specifications, the EU specifications allow the possibility that fatty acids occurring in food oils and fats, but not necessarily derived from edible oils

and fats, may be used as feedstock to prepare E 477. Therefore, it is appropriate to consider the specifications further for the possible occurrence of other chemical contaminants of oils and fats.

Esters of 3-monochloropropane-1,2-diol (3-MCPD) were found at the highest levels in refined palm oil/fat, which can be used as a raw material for propane-1,2-diol esters of fatty acids (E 477). It has been confirmed that the toxicity of 3-MCPD fatty acid esters should be considered equivalent (on a molar basis) to that of the parent compound (3-MCPD) (EFSA CONTAM Panel, 2016a, 2018). The Panel noted that there is no limit for 3-MCPD/3-MCPD esters in the specifications for propane-1,2-diol esters of fatty acids (E 477). The Panel considered that the possible presence of 3-MCPD esters in propane-1,2-diol esters of fatty acids (E 477) would need further assessment, as their presence could raise a safety concern.

Propane-1,2-diol esters of fatty acids (E 477) can be manufactured by transesterification of natural or hydrogenated fats and oils. According to EFSA (EFSA NDA Panel, 2004), industrial hydrogenation (used to produce semi-solid and solid fats that can be used for the production of foods such as margarines, shortenings and biscuits) and deodorisation (a necessary step in refining) of unsaturated vegetable oils high in polyunsaturated fatty acids is one of the three main pathways for the formation of *trans*-fatty acids in food. According to EFSA (EFSA NDA Panel, 2010), higher intakes of *trans*-fatty acids have consistently been found to be associated with an increased risk of coronary heart disease and it was recommended that *trans*-fatty acids intake should be as low as possible within the context of a nutritionally adequate diet. The Panel noted that there is no limit for *trans*-fatty acids in the specifications for propane-1,2-diol esters of fatty acids (E 477).

According to the EFSA CONTAM Panel, refined vegetable oil, which can be used for manufacturing of propane-1,2-diol esters of fatty acids (E 477), is the only identified source of glycidyl esters of fatty acids (EFSA CONTAM Panel, 2016a). Glycidyl esters of fatty acids are hydrolysed in the gastrointestinal tract to produce free glycidol, which is recognised as probably carcinogenic to humans 2A (IARC, 2000) and as a carcinogenic and genotoxic compound by the EFSA CONTAM Panel (2016a). The Panel noted that there is no limit for glycidyl esters in the specifications for propane-1,2-diol esters of fatty acids (E 477). The Panel considered that the possible presence of glycidol/glycidyl esters in propane-1,2-diol esters of fatty acids (E 477) would need further assessment, as their presence could raise a safety concern.

Rapeseed oil which contains erucic acid could be used for the manufacturing of propane-1,2-diol esters of fatty acids (E 477) (EFEMA, 2016a, (Documentation provided to EFSA n. 3)). According to the industry, only rapeseed oil low in erucic acid is used; nevertheless, it cannot be excluded that high erucic acid rapeseed oil can be used. Maximum permitted levels (MPLs) for erucic acid have been established in EU according to Commission Regulation (EU) No 696/2014 in edible oils and fats as well as in food containing fats and oils. A tolerable daily intake (TDI) of 7 mg/kg bw per day for erucic acid has been established by the EFSA CONTAM Panel based on a NOAEL of 700 mg/kg bw per day for myocardial lipodosis observed in a 7-day feeding study in young (5–7 weeks) rats and in a 2-week feeding study in newborn piglets (EFSA CONTAM Panel, 2016b). The Panel noted that there are no limits for erucic acid in the current EU specifications for propane-1,2-diol esters of fatty acids (E 477).

### 3.1.3. Manufacturing process

Propane-1,2-diol with fatty acids can be manufactured either by the direct esterification of propane-1,2-diol with fatty acids or by transesterification of propane-1,2-diol with fats and oils.

The esterification is performed with edible fatty acids, typically with commercial mixture of stearic acid and palmitic acid, at temperatures of 170–210°C with or without the use of an alkaline catalyst. During the reaction, water is removed by distillation. After removal of excess propane-1,2-diol, the reaction products consists of about 50–70% monoesters and 30–50% diesters. It is possible to control these percentages by changing the ratio between fatty acids and propane-1,2-diol. Higher concentration of the monoester can be achieved by fractional crystallisation from hexane or via a molecular distillation process (Sparsø, 2015). The fatty acids used in this process are obtained from food fats and oils by hydrolysis. The edible commercial fatty acids obtained by hydrolysis usually contain associated fatty acids in a varying amount depending on the source of the fatty acid. When direct esterification is used to produce E 477 containing specific fatty acids, the hydrolysed oils are subjected to distillation or fractionation/crystallisation prior to esterification, in order to obtain a concentrated fraction of the desired fatty acid (EFEMA, 2016a (Documentation provided to EFSA n. 3)).

Alternatively, transesterification is performed by reaction of fat (triglycerides) and propane-1,2-diol at 200–300°C in the presence of an alkaline catalyst. The reaction mixture contains mono- and diesters

of propane-1,2-diol, together with mono-, di- and triglycerides and some propane-1,2-diol, fatty acids and glycerol. Higher concentration of the monoester can be achieved by molecular distillation process (Sparsø, 2015). The fat/oil can be derived from one single source or may consist of a blend of fats and oils from different sources in order to achieve the desired fatty acid profile (EFEMA, 2016a (Documentation provided to EFSA n. 3)).

In literature, methods for the production of propane-1,2-diol fatty acid esters (mono- and diesters) using specific, commercially available, lipases are described (e.g. Shaw et al., 1989; Shaw and Lo, 1994; Sparsø, 2015). It is, however, unknown to the Panel if these methods are used for the production of the food additive E 477.

Information on the fatty acids composition of the raw materials used for the manufactured of propane-1,2-diol esters of fatty acids (E 477) as provided by industry (EFEMA, 2016a (Documentation provided to EFSA n. 3)) is presented in the EFSA opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) (EFSA ANS Panel, 2017a).

### 3.1.4. Methods of analysis in food

A sensitive high-performance liquid chromatography (HPLC) method for the determination of propane-1,2-diol esters of fatty acids in foods was developed by Murakami et al. (1997, as referred to by Wood et al. (2004)). In various foods margarine, shortening, cake powder, the additive could be selectively detected without interference after extraction followed by a derivatisation with 3,5-dinitrobenzoyl chloride. Peaks of propane-1,2-diol esters of fatty acids having fatty acids of C16:0 and C18:0 could be well separated.

Uematsu et al. (1997, only abstract in English available) published a method for the determination of propane-1,2-diol monoesters of palmitic acid and of stearic acid in food additive preparations without derivatisation using gas chromatography (GC). A wide-bore capillary column of 0.53 mm i. d. was used for separation, and a flame ionisation detector was used for detection. Coupling the GC with mass spectrometry (MS) and Fourier transform infrared resonance spectroscopy (FTIR) were used for identification.

### 3.1.5. Stability of the substance, and reaction and fate in food

According to industry (Danisco, 2010 (Documentation provided to EFSA n. 1)), the shelf life of a preparation of the food additive, which contains also added antioxidants (tocopherols), is at least 18 months when the product is stored in unbroken packaging preferably not exceeding 10°C and 80% relative humidity. The product should be kept away from sunlight and odorous products.

If unsaturated fatty acids are present in the molecule, the food additive is susceptible to autoxidation (Moonen and Bas, 2015). Unsaturated fatty acids are unstable in the presence of atmospheric oxygen. As with fats, autoxidation of fatty acids may lead to the formation of hydroperoxides, which decompose to oxygen-containing products such as aldehydes, ketones, and hydroxy compounds. The effect of atmospheric oxygen on fatty acids depends primarily on the temperature, the number of double bonds, and the molecular structure (Anneken et al., 2012).

## 3.2. Authorised uses and use levels

Maximum levels of propane-1,2-diol esters of fatty acids (E 477) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named MPLs.

Currently, propane-1,2-diol esters of fatty acids (E 477) is an authorised food additive in the EU with MPLs ranging from 1,000 to 30,000 mg/kg in 13 food categories.

Table 2 summarises the food categories that are permitted to contain propane-1,2-diol esters of fatty acids (E 477) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

**Table 2:** MPLs of propane-1,2-diol esters of fatty acids (E 477) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E-number	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products	E 477		5,000
01.8	Dairy analogues, including beverage whiteners	E 477	Only beverage whiteners	1,000
01.8	Dairy analogues, including beverage whiteners	E 477	Only milk and cream analogues	5,000
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	E 477	Only fat emulsions for baking purposes	10,000
03	Edible ices	E 477		3,000
05.2	Other confectionery including breath refreshing microsweets	E 477	Only sugar confectionery	5,000
05.3	Chewing gum	E 477		5,000
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 477		5,000
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 477	Only whipped dessert toppings other than cream	30,000
07.2	Fine bakery wares	E 477		5,000
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	E 477		1,000
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	E 477		1,000
16	Desserts excluding products covered in category 1, 3 and 4	E 477		5,000

MPL: maximum permitted level.

Propane-1,2-diol esters of fatty acids (E 477) is not authorised according to Annex III of Regulation (EC) No 1333/2008.

### 3.3. Exposure data

#### 3.3.1. Reported use levels or data on analytical levels of propane-1,2-diol esters of fatty acids (E 477)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued public calls<sup>10,11</sup> for occurrence data (use levels and/or concentration data) on propane-1,2-diol esters of fatty acids (E 477). In response to this public call, updated information on the actual use levels of propane-1,2-diol esters of fatty acids (E 477) in foods was made available to EFSA by industry. No analytical data on the concentration of propane-1,2-diol esters of fatty acids (E 477) in foods were made available by the Member States.

<sup>10</sup> <http://www.efsa.europa.eu/sites/default/files/consultation/ans091123.pdf>

<sup>11</sup> <http://www.efsa.europa.eu/sites/default/files/consultation/151012.pdf>



### Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with data on use levels ( $n = 92$ ) of propane-1,2-diol esters of fatty acids (E 477) in foods covering all 13 food categories in which propane-1,2-diol esters of fatty acids (E 477) is authorised.

Updated information on the actual use levels of propane-1,2-diol esters of fatty acids (E 477) in foods was made available to EFSA by FoodDrinkEurope (FDE) (Documentation provided to EFSA n. 6) and EFEMA (Documentation provided to EFSA n. 5). The Panel noted that EFEMA is a food additive producer/chemical supplier. Food additive producers do not directly use additives in foods, and therefore use levels reported by them are not considered at the same level as those provided by food industry. Food additive producers may recommend use levels to the food industry but the final levels used in food may, ultimately, be different. Regarding the data submitted by EFEMA, they confirmed that their data are theoretical amounts recommended to food industry. In addition, the Panel noted that the use levels from EFEMA equal the MPLs as in the Regulation (EC) No 1333/2008. Therefore, the use levels provided by EFEMA are not considered in the refined exposure scenario.

The Panel noted that 13 use levels for foods belonging to FC 03 edible ices, FC 05.4 decorations, coatings and fillings (except fruit-based fillings covered by category 4.2.4) and FC 07.2 fine bakery wares referred to niche products. Since other use levels were available for the FCs 03 and 07.2, the Panel did not include these levels in the analysis. As no other data were available for FC 05.4, the use level on the niche product was used in the refined exposure assessment.

Appendix A provides the use levels of propane-1,2-diol esters of fatty acids (E 477) in foods as reported by industry.

#### 3.3.2. Summarised data extracted from the Mintel's Global New Products Database

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 2.5 million food and beverage products of which more than 1,000,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the Mintel GNPD.<sup>12</sup>

For the purpose of this Scientific Opinion, the Mintel's GNPD<sup>13</sup> was used for checking the labelling of food and beverages products and food supplements for propane-1,2-diol esters of fatty acids (E 477) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, propane-1,2-diol esters of fatty acids (E 477) was labelled on more than 1,300 products of which 918 were found to be published in this database between January 2013 and August 2018.

Appendix B lists the percentages of the food products labelled with propane-1,2-diol esters of fatty acids (E 477) out of the total number of food products per food subcategory according to the Mintel's GNPD food classification. The percentages ranged from less than 0.1% in many food subcategories to 5.0% in the Mintel's GNPD food subcategory 'Plant Based Ice Cream & Frozen Yogurt (Dairy Alternatives)'. The average percentage of foods labelled to contain propane-1,2-diol esters of fatty acids (E 477) was 0.2%.

The main food categories labelled with propane-1,2-diol esters of fatty acids (E 477) in the Mintel's GNPD were 'Bakery' and 'Desserts and ice-cream'. These two categories correspond with the FC 07.2 (fine bakery wares) and partly with the FC 03 (edible ices) for both of which use level were reported (Section 3.3.1). However, no use levels from food industry were made available for FC 16 Desserts excluding products covered in categories 1, 3 and 4.

For the other FCs for which no data from food industry were received through the call for data (FC 01.4 Flavoured fermented milk products including heat-treated products, 01.8 Dairy analogues, including beverage whiteners (only beverage whiteners and only fat emulsions for baking purposes), FC 02.2.2 Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions, FC 05.2 Other confectionery including breath refreshing microsweets and FC 05.3 Chewing gum) very few products are labelled with propane-1,2-diol esters of fatty acids (E 477) in Mintel. For instance, only two creams were labelled with E 477 in the last 5 years, and only 5 dressings.

<sup>12</sup> Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.

<sup>13</sup> <http://www.gnpd.com/sinatra/home/> accessed on 31/8/2018.



### 3.3.3. Food consumption data used for exposure assessment

#### EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). Consumption surveys added in the Comprehensive database in 2015 were also taken into account in this assessment.<sup>9</sup>

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from the following population groups were used for the exposure assessment: infants, toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 3).

**Table 3:** Population groups considered for the exposure estimates of propane-1,2-diol esters of fatty acids (E 477)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers <sup>(a)</sup>	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children <sup>(b)</sup>	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly <sup>(b)</sup>	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Netherlands, Sweden, UK

(a): The term 'toddlers' in the EFSA Comprehensive Database corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.

(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, the FoodEx food codes were matched to the FCS food categories.

#### Food categories considered for the exposure assessment of propane-1,2-diol esters of fatty acids (E 477)

The food categories in which the use of propane-1,2-diol esters of fatty acids (E 477) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

The restriction 'only whipped dessert toppings other than cream' of FC 05.4 'Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4', could not be differentiated from all

decorations, coatings and fillings in the EFSA Comprehensive Database. Considering that 'only whipped dessert toppings other than cream' represents a small part of the food category, the MPL of 5,000 mg/kg was taken into account in the regulatory maximum exposure assessment scenario for FC 05.4. As the MPL from the whole food category (5,000 mg/kg) is lower than that for the 'only whipped dessert toppings other than cream' (30,000 mg/kg), this may have resulted in an underestimation of the exposure. Use levels were reported only for the FC 05.4 with the MPL of 5,000 mg/kg, however, the levels provided were used for the whole FC 05.4.

For the following food categories, the restrictions/exceptions which apply to the use of propane-1,2-diol esters of fatty acids (E 477) could not be taken into account, and the whole food category was considered in the exposure assessment. This applied to two food categories and may have resulted in an overestimation of the exposure:

- 01.8 Dairy analogues, including beverages whiteners, only beverages whiteners and only milk and cream analogues. It was not possible to differentiate between all dairy analogues and therefore the whole food category of dairy analogues was taken into account at the highest MPL (5,000 mg/kg for milk and cream analogues).
- 02.2.2 Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions, only fat emulsions for baking purposes. It was not possible to select FC 02.2.2 (only the consumption of fat emulsions for baking purposes) and considering that many fat emulsions could be used for baking, the whole FC 02.2 was taken into account excluding butters (FC 02.2.1).

Propane-1,2-diol esters of fatty acids (E 477) is also allowed in FCs 13.2 and 13.3. Food items under these food categories, consumed by children, adolescents, adults and the elderly, may be very diverse and, in addition, there is very limited information on their consumption present in the EFSA Comprehensive Database. Therefore, eating occasions belonging to these food categories were reclassified under food categories in accordance to their main component.

For the refined exposure scenario, eight additional food categories were not taken into account because only recommended levels from EFEMA were provided to EFSA (Appendix C). For the remaining food categories, the refinements considering the restrictions/exceptions as set in Annex II to Regulation No 1333/2008 were applied.

Overall, for the regulatory maximum level exposure scenario, 11 food categories were included, while for the refined scenarios, only three food categories were included in the present exposure assessment to propane-1,2-diol esters of fatty acids (E 477) (Appendix C).

### 3.4. Exposure estimates

#### 3.4.1. Exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive

The Panel estimated the chronic dietary exposure to propane-1,2-diol esters of fatty acids (E 477) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) was calculated by multiplying the use levels of propane-1,2-diol esters of fatty acids (E 477) per food category (Appendix C) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). On the basis of these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not estimated.

Exposure assessment to propane-1,2-diol esters of fatty acids (E 477) was carried out by the FAF Panel based on two different sets of concentration data: (1) MPLs as set down in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*), and (2) reported use levels (defined as the *refined exposure assessment scenario*). These two scenarios are discussed in detail below.

## Regulatory maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario of propane-1,2-diol esters of fatty acids (E 477) was based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008 and listed in Table 2 (Appendix C).

The Panel considers the exposure estimates derived following this scenario as the most conservative since it is assumed that that the population will be exposed to the food additive present in food at the MPL over a longer period of time.

## Refined exposure assessment scenario

The refined exposure assessment scenario is based on use levels reported by food industry. This exposure scenario can consider only food categories for which these data were available to the Panel.

Appendix C summarises the use levels of propane-1,2-diol esters of fatty acids (E 477) used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on two model populations:

- The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to propane-1,2-diol esters of fatty acids (E 477) present at the maximum reported use for one food category. This exposure estimate is calculated as follows:
  - Combining food consumption with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.
- The non-brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to propane-1,2-diol esters of fatty acids (E 477) present at the mean reported use levels in food. This exposure estimate is calculated using the mean of the typical reported use levels for all food categories.

## Dietary exposure to propane-1,2-diol esters of fatty acids (E 477)

Table 4 summarises the estimated exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive in six population groups (Table 3) according to the different exposure scenarios. Detailed results per population group and survey are presented in Appendix D.

**Table 4:** Summary of dietary exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive in the regulatory maximum level exposure assessment scenario and in the refined exposure assessment scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks– 11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
<b>Regulatory maximum level exposure assessment scenario</b>						
• Mean	0.7–17.4	22.4–72.7	14.3–64.4	5.7–22.0	1.1–11.0	0.9–9.2
• 95th percentile	2.2–74.0	57.4–189	37.1–159	15.4–56.4	4.0–29.9	3.1–24.4
<b>Refined estimated exposure assessment scenario</b>						
<b>Brand-loyal scenario</b>						
• Mean	< 0.1–6.7	0.8–18.3	0.4–18.8	0.1–9.3	0.7–6.7	0.7–6.4
• 95th percentile	< 0.1–28.5	4.0–45.4	1.3–46.9	0.8–25.0	2.9–20.0	2.6–17.4
<b>Non-brand-loyal scenario</b>						
• Mean	< 0.1–2.4	0.3–6.5	0.2–6.7	0.1–3.3	0.3–2.4	0.3–2.3
• 95th percentile	< 0.1–10.2	1.4–16.1	0.5–16.7	0.3–8.9	1.1–7.1	0.9–6.2

In the *regulatory maximum level exposure assessment scenario*, the mean exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive ranged from 0.7 mg/kg bw per day in infants to 72.7 mg/kg bw per day in toddlers. The high (95th percentile) exposure ranged from 2.2 mg/kg bw per day in infants to 188.7 mg/kg bw per day in toddlers.

In the *brand-loyal refined estimated exposure scenario*, the mean exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive ranged from < 0.1 to 18.8 mg/kg bw per

day, and the high exposure from < 0.1 to 46.9 mg/kg bw per day. In the *non-brand-loyal scenario*, the mean exposure ranged from < 0.1 to 6.7 mg/kg bw per day, and the high exposure from < 0.1 to 16.7 mg/kg bw per day. In all these refined exposure estimates, the lowest exposure was estimated for infants and the highest for children.

### Main food categories contributing to exposure for the general population

#### Main food categories contributing to exposure to propane-1,2-diol esters of fatty acids (E 477) using the regulatory maximum level exposure assessment scenario

In the *regulatory maximum level exposure assessment scenario*, the main contributing food categories to the total mean exposure estimates were FC 01.4 Flavoured fermented milk products and FC 07.2 Fine bakery wares for infants, toddlers, children and adolescents. For adults and the elderly, the main contributing food category was FC 07.2 Fine bakery wares (see Appendix E for more details).

#### Main food categories contributing to exposure to propane-1,2-diol esters of fatty acids (E 477) using the refined exposure assessment scenario

The main contributing food category for both the *brand-loyal* and *non-brand-loyal refined estimated exposure scenarios* was FC 07.2 Fine bakery wares for all population groups, followed by FC 03 Edible ices (see Appendix E for more details).

### Uncertainty analysis

Uncertainties in the exposure assessment of propane-1,2-diol esters of fatty acids (E 477) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

**Table 5:** Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction <sup>(a)</sup>
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/-
Use of data from food consumption surveys covering only a few days to estimate high percentiles (95th) long-term (chronic) exposure	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties to which types of food the levels refer to	+/-
Concentration data: <ul style="list-style-type: none"> <li>use levels considered applicable to all foods within an entire food category, whereas on average 0.2% of the foods belonging to food categories with foods labelled with additive were labelled with the additive</li> </ul>	+
The 3 food categories which were taken into account in the refined exposure assessment scenarios out of all authorised food categories (N = 13), corresponded to 1–92% of the amount (grams of foods by body weight) of foods consumed which could contain the food additive	–
Food categories selected for the regulatory maximum exposure assessment scenario: one food category at a lower MPL/lower use level due to missing FoodEx linkage	–
Food categories selected for the regulatory maximum exposure assessment scenario: inclusion of food categories without considering the restriction/exception (n = 2 for all scenarios out of 13 food categories)	+
Food categories included in the refined exposure assessment scenario: no data for certain food categories which were therefore not considered in the refined exposure estimates (n = 8/13 food categories)	–
Regulatory maximum level exposure assessment scenario: <ul style="list-style-type: none"> <li>exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008</li> </ul>	+
Refined exposure assessment scenarios: <ul style="list-style-type: none"> <li>exposure calculations based on the maximum or mean levels (reported use from industries)</li> </ul>	+/-

+, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Propane-1,2-diol esters of fatty acids (E 477) is authorised in 13 food categories. The Panel calculated that out of the foods authorised to contain propane-1,2-diol esters of fatty acids (E 477) according to Annex II to Regulation (EC) No 1333/2008, 1% (infants) to 92% (children) of the amount of food consumed (by weight) per population group was reported to potentially contain propane-1,2-diol esters of fatty acids (E 477) as a food additive.

In the Mintel GNPD, 18 food subcategories are labelled to contain propane-1,2-diol esters of fatty acids (E 477) (Appendix B). Industry provided use levels for 3 food categories according to Regulation (EC) No 1333/2008 that covers 10 of the Mintel subcategories. These 10 food subcategories represented approximately 91% of the food products labelled with propane-1,2-diol esters of fatty acids (E 477) in the database. Together with the observation that the average percentage of foods labelled to contain propane-1,2-diol esters of fatty acids (E 477) was 0.2% while in the assessment it was assumed that 100% of the foods belonging to an authorised food category contained the additive, the Panel estimates that the underestimation of the exposure in the refined exposure scenarios due to the limited number of food categories considered was limited.

The Panel noted that some foods found to be labelled with E 477 in the Mintel's GNPD were not authorised to contain E 477 according to EU legislation. These foods belonged to the food subcategories Dressings & Vinegar, Beverage Mixes and Bread & Bread Products. However, the number of foods was very limited (Appendix B).

Overall, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive according to Annex II, in European countries considered in the EFSA European database for both the regulatory maximum level exposure assessment scenario and the refined exposure assessment scenario.

### 3.4.2. Exposure to propane-1,2-diol from propane-1,2-diol esters of fatty acids (E 477)

The Panel noted that propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) would add to the exposure to the food additives propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E405) previously re-evaluated by EFSA (EFSA ANS Panel, 2018a,b).

The total content of propane-1,2-diol in propane-1,2-diol esters of fatty acids (E 477) amounts up to a maximum of 31% by weight according to the EU specification. The Panel considered a maximum release of 31% as a worst case on which exposure was estimated.

Based on the highest P95 exposure level observed in the *regulatory maximum level exposure assessment scenario* for propane-1,2-diol esters of fatty acids (E 477) (188.7 mg/kg bw per day for toddlers), the highest exposure to propane-1,2-diol was calculated to be 58.5 mg/kg bw per day. In the *non-brand-loyal scenario*, the highest P95 exposure to propane-1,2-diol esters of fatty acids (E 477) was 16.7 mg/kg bw per day for children, resulting in an exposure of 5.2 mg propane-1,2-diol/kg bw per day.

Overall, the Panel considered that an accurate exposure assessment for propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) was influenced by the same uncertainties as mentioned in section 3.4.1.

## 3.5. Biological and Toxicological data

The Panel also considered in this opinion absorption, distribution, metabolism and excretion (ADME) and toxicological data on propane-1, 2-diol and fatty acids, the two hydrolytic derivatives of propane-1,2-diol esters of fatty acids. Propane-1,2-diol (E 1520) and certain fatty acids (E 570) have been recently re-evaluated for their safety of use as food additives (EFSA ANS Panel 2017b, 2018a).

### 3.5.1. Absorption, distribution, metabolism and excretion

#### 3.5.1.1. Propane-1,2-diol esters of fatty acids

##### *In vitro* studies

The hydrolysis of propane-1,2-diol monostearate was studied *in vitro*. At an initial concentration of 0.2 mM, this ester was shown to be hydrolysed by pancreatic lipase (addition of 'pancreas extracts', no further details) to the extent of 37% in 2 h and about 70% in 15 h at a temperature of 40°C (Balls and Matlock, 1938).



Long et al. (1958a) obtained similar results in an *in vitro* study using propane-1,2-diol distearate as the substrate. The hydrolysis rate was calculated by dividing the moles of free fatty acid analysed by the moles of the substrate initially available. At a concentration of 4% of substrate, the enzyme steapsin (concentration 0.6%, temperature of 30°C, pH 8.35) hydrolysed about 70% of propane-1,2-diol distearate within 19 h.

### **In vivo studies**

The biological disposition of <sup>14</sup>C-labelled propane-1,2-diol ester of distearate after oral administration by gavage, was studied in male and female Wistar rats (Long et al., 1958a,b).

In different experiments, the authors used 1-<sup>14</sup>C-labelled propane-1,2-diol distearate (PD\*DS) or the <sup>14</sup>C-carboxyl-labelled distearate- propane-1,2-diol ester (PDDS\*).

In a first experiment (Long et al., 1958a), oral absorption was determined by measurement of the residual radioactivity in the gastrointestinal tract at different time points after oral administration (n = 2–5 rats per group). After administration of PDDS\*, the authors calculated an absorption of 2%, 11%, 23%, 19% or 33% of applied radioactive dose 0, 1, 3, 5 or 8 h after gavage, respectively. Using the same experimental design using PD\*DS, the absorption of PD\*DS radioactivity was 25% 3 h after oral application.

Contrasting results were obtained in a further study in rats having received by gavage PDDS\* (n = 2) or PD\*DS (n = 1) (Long et al., 1958a). In the two rats having received PDDS\*, 65.8% of applied radioactivity was found in faeces, 17.5% in exhaled CO<sub>2</sub>, 6.4% in urine, 6.2% in organs and 10.8% in carcass; the total recovery was 106.8%. The results in the one rat which had been given PD\*DS was somewhat different with a 99.8% absorption, calculated from the low level of radioactivity in the gastrointestinal content and the high <sup>14</sup>CO<sub>2</sub> exhalation.

In a second study Long et al. (1958b), using the same experimental design investigated the identification of *in vivo* digestion products, the uptake by the intestinal lymphatics, and the mechanism of transport of propane-1,2-diol ester of distearate (Long et al., 1958b). Chromatographic separation of the radioactivity revealed that after administration of PD\*DS hydrolysis products were present in the content of the gastrointestinal tract; however, unhydrolysed PD\*DS was also detected. Following administration of PDDS\*, propane-1,2-diol monostearate and stearic acid were found. In other animals, radioactivity in the lymph was determined and lymph extracts were analysed by paper and column chromatography. In the lymph, most radioactivity was detected in the first 6 h after gavage. 23.6% of the applied radioactivity from PDDS\* occurred within 48 h and 12.4% after application of PD\*DS. The authors confirmed the presence of propane-1,2-diol distearate in the lymph. According to the authors, the presence of propane-1,2-diol distearate in the lymph could be explained by re-synthesis of the diester from its hydrolytic products in the course of the absorption process similar to the process by which the glycerol esters of fatty acids enter the lymph.

Overall, the *in vitro* experiments showed that propane-1,2-diol esters of stearate are partially hydrolysed by pancreatic lipase; however hydrolysis was slow with only 30% hydrolysis in 3 h and 70% in 15 h. As the passage through the small intestine has a duration of 6–8 h, unhydrolysed propane-1,2-diol esters of stearate will be present in the gastrointestinal tract for absorption. The presence of propane-1,2-diol distearate in the lymph has been demonstrated.

## **3.5.2. Acute toxicity**

### **3.5.2.1. Propane-1,2-diol esters of fatty acids**

Acute oral toxicity of propane-1,2-diol ester of lauric acid (no further details) were studied in rats (no further details available) (Stepan Company, 1996, as referred to by Johnson, 1999). The LD<sub>50</sub> was greater than 34,600 mg/kg bw and the test substance was classified as practically nontoxic.

No lethal effects occurred in 10 rats after gavage of 5,000 mg/kg bw undiluted propane-1,2-diol ester of stearic acid (CTFA, 1972, as referred to by CIR, 1983).

The LD<sub>50</sub> of propane-1,2-diol ester of stearic acid was > 2,750 mg/kg bw after oral application of this dose level in an unknown solvent (concentration 55%) to five rats (CTFA, 1976, as referred to by CIR, 1983).

The same substance was tested in groups of five rats at eight dose levels ranging from 1,000 to 32,000 mg/kg bw; the solvent was propane-1,2-diol (concentration unknown). No clinical signs were detected after gavage of ≤ 2,000 mg/kg bw. At 4,000 and 8,000 mg/kg bw, unkempt coats were observed for 12–16 h. Lethargy, staggering gait, impaired locomotion and unkempt coats were induced after application of ≥ 16,000 mg/kg bw. Two animals died on day 2 at 25,000 mg/kg bw but all



survivors appeared normal 4 days after gavage. All five died on day 1 at 32,000 mg/kg bw. The authors reported an oral LD<sub>50</sub> of 25,800 mg/kg bw (Bio Toxicology Labs, 1975, as referred to by CIR, 1983).

Propane-1,2-diol ester of stearic acid (self-emulsifying) applied via gavage to 10 rats resulted in no mortality at a dose of 10,000 mg/kg bw (no further details; CTFA, 1975, as referred to by CIR, 1983).

The same substance in corn oil (concentration: 50%) was applied to groups of five rats at dose levels ranging between 1,000 and 32,000 mg/kg bw. No deaths were induced. The LD<sub>50</sub> was > 32,000 mg/kg bw (BTL, 1975, as referred to by CIR, 1983).

### 3.5.2.2. Propane-1,2-diol (E 1520)

The Panel considered that the data from acute toxicity studies in mice, rats, hamsters and rabbits indicated low acute toxicity of propanediol-1,2-diol (EFSA ANS Panel, 2018a).

Overall, the Panel considered the acute toxicity of propane-1,2-diol esters of fatty acids and propane-1,2-diol to be low.

### 3.5.3. Short-term and subchronic toxicity

#### 3.5.3.1. Propane-1,2-diol esters of fatty acids

##### *Rats*

Six 21-day-old female rats were fed for 70 days a diet containing 60% propane-1,2-diol ester of lard fatty acids (no further details) (Lepkovsky et al., 1935). Data on a control group were not given. The histopathological examination of the kidneys of 2 animals of this group (sacrificed 40 days after start of exposure period) showed no lesions.

Groups of 10 male and 10 female Sprague–Dawley rats received for 90 days a diet containing 2.5%, 5% or 10% succistearin<sup>14</sup> (equivalent to 0, 390, 780 or 1,560 mg propane-1,2-diol monostearate/kg bw per day); the control group was fed with soybean oil (King et al., 1971). The total fat content in each diet was 21%. No clinical symptoms were observed and no effects on body weight gain. Haematology, urinalysis and comparison of organ weight data revealed no treatment related effects as well as gross and microscopic pathology. The authors reported also no toxic effects in a second feeding study in rats after a 6-months exposure period and using a similar experimental design.

In a 13-week study, rats (n = 48 per group) were fed diets containing 0%, 1.5%, 3.36% or 7.52% of propane-1,2-diol monostearate (equivalent to 0, 1,350, 3,024 or 6,768 mg/kg bw per day (Brandner, 1973; as referred to by JECFA, 1974a). Mono- and diglycerides were added to the diets to bring the total fat to 7.52%. Body weight gain was not affected. At termination, there was no difference between the groups in respect of relative organ weights of the adrenals, gonads, heart, kidneys, liver, spleen and brain. Histopathology, clinical chemistry (blood glucose, blood urea nitrogen, plasma cholesterol, plasma glutamate pyruvate transaminase), haematology (haemoglobin, haematocrit, white cell count, differential white blood cell counts, clotting time) or urinary analyses revealed no treatment-related effects. The NOAEL identified in this study for propane-1,2-diol monostearate was 7.52% in the diet equivalent to 6,768 mg/kg bw per day, the highest dose tested.

##### *Dogs*

No treatment-related effects were detected in Beagle dogs (n = 4 per group) exposed for 6 months via the diet containing 0%, 5% or 10% succistearin (17.3% of propane-1,2-diol monostearate) (equivalent to 0, 216 or 432 mg propane-1,2-diol monostearate/kg bw per day); the control group was fed with soybean oil (King et al., 1971).

### 3.5.3.2. Propane-1,2-diol (E 1520)

No treatment-related effects were observed in subchronic toxicity studies in which propane-1,2-diol was administered by gavage (1,000 mg/kg bw per day) to mice, rats, dogs and monkeys for 92–97 days (Thackaberry et al., 2010; EFSA ANS Panel, 2018a).

Overall, in a 13-week study in rats (Brandner, 1973; as referred to by JECFA, 1974a) with propane-1,2-diol monostearate a NOAEL of 6,768 mg/kg bw per day, the highest dose tested, was identified. In addition, no treatment-related effects were observed when propane-1,2-diol monostearate was fed to rats for 90 days (King et al., 1971) at the highest dose tested 1,560 mg/kg bw per day. In dogs (King

<sup>14</sup> The test item 'succistearin' (stearoyl propylene glycol hydrogen succinate) used contained an amount of 17.3% of propane-1,2-diol monostearate.

et al., 1971), no treatment-related effects were observed after feeding 432 mg propane-1,2-diol monostearate/kg bw per day, the highest dose tested, for 6 months.

### 3.5.4. Genotoxicity

#### 3.5.4.1. Propane-1,2-diol esters of fatty acids

No mutagenic properties were detected in a bacterial reverse mutation test. *Salmonella* Typhimurium strains TA92, TA94, TA98, TA100, TA1535 and TA1537 were used in a pre-incubation assay to determine the mutagenic activity of propane-1,2-diol ester of fatty acids (no further data on the test substance); the vehicle was dimethylsulfoxide. Duplicate plates were used for each of six different concentrations; the maximal concentration was 10 mg/plate (no further data). This concentration did not induce bacteriotoxicity and is above the maximum concentration recommended in current guidelines. For metabolic activation (MA), liver S9 microsomes of rats treated with polychlorinated biphenyls were added. No mutagenic activity was reported with or without MA (Ishidate et al., 1984).

In bacterial reverse mutation tests with propane-1,2-diol monostearate (FDA 73-57, no further data), no mutagenic activity was found even at extremely high concentrations of 5% test substance in the medium (Litton Bionetics Incorporated, 1975). The strains *S. Typhimurium* TA1535, TA1537 and TA1538 were tested in the plate incorporation assay (duplicate plates) with (liver S9-mix from mouse, rats or monkey) and without MA. The vehicle was dimethylsulfoxide. Precipitates were observed suggesting limited solubility. While the positive controls resulted in adequate mutagenic activity in comparison to the vehicle controls, the test item did not induce an increase in the frequency of revertants. Also, no mutagenic effects were reported in a second trial using the suspension test at concentrations of 2.5%, 5% or 10% in medium.

The Panel noted that the studies described above were not fully consistent with OECD TG 471 since strains *S. Typhimurium* TA102 or *Escherichia coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) were not included.

Propane-1,2-diol ester of fatty acids (no further data on the test substance) was tested in a chromosome aberration test in the Chinese hamster fibroblast cell line CHL (vehicle: dimethylsulfoxide) (Ishidate et al. (1984). The cells were exposed to 3 concentrations for 24 and 48 h, only without MA; the maximum non-cytotoxic concentration tested was 0.125 mg/mL (no further details). The cytotoxic effects were studied in preliminary tests and the concentration resulting in 50% cell-growth inhibition was chosen as highest concentration for genotoxicity testing. One hundred metaphases per concentration were analysed for polyploid cells and structural chromosomal aberrations. Chromosome and chromatid gaps were included in the evaluation of clastogenic effects. The exposure to propane-1,2-diol ester of fatty acids did not result in polyploidy or clastogenic effects. The Panel, however, noted that the reliability of these results is limited because they were not reported in detail and chromosome and chromatid gaps were included in the evaluation.

Propane-1,2-diol monostearate was tested in the *Saccharomyces cerevisiae* gene mutation assay using the strains D4 (Litton Bionetics Incorporated, 1975). Forward mutations at the *ade-* or *try-* locus were measured at concentrations of 0.5%, 1% or 2% test item in medium. The vehicle was dimethylsulfoxide. Precipitates were observed suggesting limited solubility. No mutagenicity was induced in the presence and absence of a MA system. The Panel noted that this assay does not belong to the assays recommended by the Scientific Committee for regulatory purposes (EFSA Scientific Committee, 2011).

#### 3.5.4.2. Propane-1,2-diol

According to a recent re-evaluation, propane-1,2-diol did not raise a concern with respect to genotoxicity when used as a food additive (EFSA ANS Panel, 2018a).

Overall, based on the available *in vitro* tests of limited reliability performed with propane-1,2-diol esters of fatty acids that did not show indications for a genotoxic potential and taking into account that propane-1,2-diol did not raise a concern with respect to genotoxicity, the Panel considered that the fatty acid esters of propane-1,2-diol (E 477) did not raise a concern for genotoxicity.

### 3.5.5. Chronic toxicity and carcinogenicity

#### 3.5.5.1. Propane-1,2-diol esters of fatty acids

No chronic or carcinogenicity studies were available to the Panel.

### 3.5.5.2. Propane-1,2-diol (E 1520)

Propane-1,2-diol did not show adverse effects in a 2-year study in dogs (Weil et al., 1971). Furthermore, no neoplastic findings were reported in a 2-years study in rats administered 2,500 mg propane-1,2-diol/kg bw per day, the highest dose tested, for 2 years (Gaunt et al., 1972).

### 3.5.6. Reproductive and developmental toxicity

#### 3.5.6.1. Propane-1,2-diol esters of fatty acids

No studies were available to the Panel.

#### 3.5.6.2. Propane-1,2-diol (E 1520)

In two reproductive toxicity studies (mice and rats) and six developmental studies in mice, rats, hamsters and rabbits, no treatment-related effects were observed at the highest doses tested ( $\geq 1,000$  mg propane-1,2-diol/kg bw per day) (EFSA ANS Panel, 2018a).

### 3.5.7. Studies with other emulsifiers

Propane-1,2-diol esters of fatty acids (E 477) is included in the list of EFEMA index of food emulsifiers (EFEMA, 2015).

In several recent studies, some other emulsifiers have been reported to alter the gut microbiota, to promote gut inflammation, obesity and to impair glycaemic control (Swidsinski et al., 2009a,b; Renz et al., 2012; Merga et al., 2014; Cani and Everard, 2015; Chassaing et al., 2015; Romano-Keeler and Weitkamp, 2015; Lecomte et al., 2016; Chassaing et al., 2017; Nejrup et al., 2017; Shah et al., 2017; Jiang et al., 2018; Holder and Chassaing, 2018; Viennois and Chassaing, 2018). No such data are available for propane-1,2-diol esters of fatty acids.

## 3.6. Discussion

JECFA evaluated propane-1,2-diol esters of fatty acids in 1974 and stated that there is evidence for hydrolysis of propane-1,2-diol esters of fatty acids resulting in the products propane-1,2-diol, for which an ADI of 25 mg/kg bw per day has previously established, and fatty acids. JECFA established an ADI of 25 mg/kg bw per day for propane-1,2-diol esters of fatty acids, this ADI was expressed as propane-1,2-diol (JECFA, 1974a) that was endorsed by the SCF (1978).

The safety of propane-1,2-diol and specific fatty acids has recently been assessed in the opinions on the re-evaluation of propane-1,2-diol (E 1520) (EFSA ANS Panel, 2018a) and of fatty acids (E 570) (EFSA ANS Panel, 2017b). No adverse effects of specific fatty acids were identified in studies reported in the EFSA opinion (EFSA ANS Panel, 2017b) and an ADI of 25 mg/kg bw per day was established for propane-1,2-diol (E 1520) (EFSA ANS Panel, 2018a).

*In vitro* experiments showed incomplete hydrolysis of propane-1,2-diol esters of stearate. In *in vivo* studies, the presence of propane-1,2-diol distearate in the lymph has been demonstrated.

The Panel considered that the acute toxicity of propane-1,2-diol esters of fatty acids was low.

In a 13-week study in rats (Brandner, 1973; as referred to by JECFA, 1974a) with propane-1,2-diol monostearate a NOAEL of 6,768 mg/kg bw per day, the highest dose tested, was identified. In addition, no treatment-related effects were observed when propane-1,2-diol monostearate was fed to rats for 90 days at the highest dose tested of 1,560 mg/kg bw per day (King et al., 1971). In dogs, no treatment-related effects were observed after feeding 432 mg propane-1,2-diol monostearate/kg bw per day, the highest dose tested (King et al., 1971).

Based on the available *in vitro* tests of limited reliability performed with propane-1,2-diol esters of fatty acids that did not show indications for a genotoxic potential and taking into account that propane-1,2-diol did not raise a concern with respect to genotoxicity, the Panel considered that also the fatty acid esters of propane-1,2-diol (E 477) did not raise a concern for genotoxicity.

No chronic toxicity, carcinogenicity, reproductive and developmental toxicity studies with propane-1,2-diol esters of fatty acids were available to the Panel.

The Panel noted that toxicological studies with substances<sup>15</sup> that fall under the definition of the food additive E 477 are registered in REACH.<sup>16</sup> According to the REACH registrants, these toxicological

<sup>15</sup> CAS Registry Number 68583-51-7; CAS Registry Number 84988-75-0; CAS Registry Number 1323-39-3.

<sup>16</sup> <https://echa.europa.eu/>

studies, performed mainly according to the appropriate OECD guidelines and in compliance with good laboratory practice (GLP), did not show adverse effects up to the highest doses tested (1,000 mg/kg bw per day for the subchronic and prenatal toxicity study. However, these studies were not available to the Panel for their evaluation.

The Panel considered that any potential adverse effect of propane-1,2-diol ester of fatty acids would be due to propane-1,2-diol. Therefore, the ADI of the food additive E 477 was determined by the amount of free propane-1,2-diol and the propane-1,2-diol released from the food additive after hydrolysis. According to the EU specification, the concentration of free and bound propane-1,2-diol amounts to a maximum of 31% on a weight basis. On the worst-case assumption that 100% of propane-1,2-diol (free and bound) would be systemically available and considering the ADI for propane-1,2-diol of 25 mg/kg bw per day, this corresponds to an ADI of 80 mg/kg bw per day for propane-1,2-diol ester of fatty acids.

Propane-1,2-diol esters of fatty acids (E 477) is authorised in 13 food categories according to Annex II to Regulation (EC) No 1333/2008. Industry provided use levels for propane-1,2-diol esters of fatty acids (E 477). No analytical data on the concentration of this food additive in foods were made available by the Member States.

Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive according to Annex II was calculated for different exposure scenarios based on MPLs and the provided use levels (Section 3.4). Use levels were reported from food industry for only three food categories out of the 13 in which the additive is authorised. The Panel noted that 63 (71%) out of the 92 reported use levels were related to the use of propane-1,2-diol esters of fatty acids (E 477) in edible ices (FC 03) (Appendix A). This reported use was in line with the information from the Mintel's GNPD, as the main subcategories labelled with the additive were ice-creams (Appendix B).

The Panel considered that for the main food category (fine bakery wares) contributing to the exposure estimates, brand-loyalty would not be expected and therefore selected the refined non-brand loyal scenario as the most relevant exposure scenario for its safety evaluation. Dietary exposure to propane-1,2-diol esters of fatty acids (E 477) via this exposure scenario was up to 6.7 mg/kg bw per day at the mean level in children and up to 16.7 mg/kg bw per day at the high (P95) level in children.

The exposure assessment was influenced by several uncertainties (Table 8). Overall, it was considered that the exposure was most likely overestimated. For a more detailed discussion on the uncertainties, see Section 3.4.1.

The Panel noted that the exposure estimates were based on reported use levels of propane-1,2-diol esters of fatty acids (E 477). If current practice changes, these refined estimates may no longer be representative and should be updated.

The Panel noted that propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) would add to the exposure to the food additives propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E 405) previously re-evaluated by the Panel (EFSA ANS Panel, 2018a,b). Propane-1,2-diol may be released from propane-1,2-diol esters of fatty acids (E 477) at a maximum of 31% according to the EU specification. Based on this, and considering the highest P95 exposure level observed, the highest exposure to propane-1,2-diol was calculated to be, in the *non-brand-loyal scenario*, 5.2 mg/kg bw propane 1,2 diol per day in infants (released from 16.7 mg/kg bw per day of propane-1,2-diol esters of fatty acids (E 477)) as this was considered to be the most relevant exposure scenario for this assessment.

## 4. Conclusions

Considering the overall metabolic and toxicity database, the Panel confirmed the previously established ADI for propane-1,2-diol esters of fatty acids (E 477) of 25 mg/kg bw per day expressed as propane 1,2 diol. This corresponds to an ADI for propane-1,2-diol esters of fatty acids (E 477) of 80 mg/kg bw per day, based on the concentration of free and bound propane-1,2-diol amounting to a maximum of 31% as laid down in the EU specification.

The Panel concluded that there would be no safety concern at the reported use levels for propane-1,2-diol esters of fatty acids (E 477) as a food additive since the exposure estimates from the refined non-brand loyal scenario did not exceed the ADI of E 477 in any of the population groups. The Panel however noted that propane-1,2-diol released from propane-1,2-diol esters of fatty acids (E 477) would give rise to an increased exposure to propane-1,2-diol resulting from the use of food additives propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E 405) previously re-evaluated by the Panel (EFSA ANS Panel, 2018a,b). Therefore, the Panel aims to explore the feasibility of establishing a group ADI for those food additives that result in an exposure to propane-1,2-diol, such as propane-



1,2-diol esters of fatty acids (E 477), propane-1,2-diol (E 1520) and propane-1,2-diol alginate (E 405). The Panel will also consider performing a combined exposure assessment to propane-1,2-diol resulting from the use of these food additives.

## 5. Recommendations

The Panel recommended that the European Commission considers:

- 1) lowering the current limits for toxic elements (arsenic, lead, mercury and cadmium) in the EU specifications propane-1,2-diol esters of fatty acids (E 477) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- 2) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for *trans*-fatty acids since propane-1,2-diol esters of fatty acids (E 477) can be manufactured by transesterification of hydrogenated fats and/or oils, which contain significant amounts of *trans*-fatty acids.
- 3) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for glycidyl esters/glycidol and 3-MCPD esters, because it is likely that residues of those substances occur in the food additive propane-1,2-diol esters of fatty acids (E 477), if they were present in the raw materials used in the manufacturing of the food additive by transesterification.
- 4) revising the EU specifications for propane-1,2-diol esters of fatty acids (E 477) including maximum limits for erucic acid since erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of propane-1,2-diol esters of fatty acids (E 477).

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- 2) EFEMA (European Food Emulsifier Manufacturers' Association), 2009. EFEMA index of food emulsifiers. September 2009, 5<sup>th</sup> Edition. Submitted by EFEMA, January 2011.
- 3) EFEMA (European Food Emulsifier Manufacturers' Association), 2011. Re-evaluation of food emulsifiers. Use of supplementary information collected via REACH. Austen Business Solutions Ltd 20/1/2011. Submitted by EFEMA, January 2011.
- 4) EFEMA (European Food Emulsifiers Manufacturers Association), 2016a. EFEMA response to EFSA's request for information on the chemical identity of each individual fatty acid including their percentage in the sources used for each food additive listed in the call for technical data. Submitted by EFEMA on 30 September 2016.
- 5) EFEMA (European Food Emulsifiers Manufacturers Association), 2016b. Data on use levels of propane-1,2-diol esters of fatty acids in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2015). Submitted to EFSA on 31 May 2016.
- 6) FDE (FoodDrinkEurope), 2016. Data on use levels of propane-1,2-diol esters of fatty acids in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2015). Submitted to EFSA on 31 May 2016.
- 7) Pre-evaluation document prepared by Fraunhofer, December 2013.

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## Abbreviations

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, excretion
ANS	EFSA Scientific Panel on Food Additives and Nutrient Sources added to Food

bw	body weight
CAS	Chemical Abstracts Service
CIR	Cosmetic Ingredient Review
CTFA	Cosmetic, Toiletry and Fragrance Association
CONTAM	EFSA Panel on Contaminants in Food Chain
EFEMA	European Food Emulsifiers Manufacturers Association
EINECS	European Inventory of Existing Chemical Substances
FAF	EFSA Panel on Food Additives and Flavourings
FAO	Food and Agriculture Organization of the United Nations
FCs	food categories
FCS	food categorisation system
FDE	Food Drink Europe
FTIR	fourier transform infrared resonance spectroscopy
GC	gas chromatography
GNPD	Global New Products Database
HPLC	high-performance liquid chromatography
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LD <sub>50</sub>	lethal dose, median
MA	metabolic activation
MCPD	monochloropropane-1,2-diol
MPL	maximum permitted level
MS	mass spectroscopy
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
QS	<i>quantum satis</i>
SCF	Scientific Committee on Food
TDI	tolerable daily intake
TemaNord	is a publishing series for results of the often research-based work that working groups or projects under Nordic Council of Ministers have put in motion
TLC	thin-layer chromatography
WHO	World Health Organization

**Appendix A – Summary of reported use levels of propane-1,2-diol esters of fatty acids (E 477) provided by industry (mg/kg)**

**Appendix B – Number and percentage of food products labelled with propane-1,2-diol esters of fatty acids (E 477) out of the total number of food products present in the Mintel GNPD per food subcategory between 2013 and 2018**

**Appendix C – Concentration levels of propane-1,2-diol esters of fatty acids (E 477) used in the exposure assessment scenarios (mg/kg or mL/kg as appropriate)**

**Appendix D – Summary of total estimated exposure to propane-1,2-diol esters of fatty acids (E 477) from its use as a food additive for the regulatory maximum level exposure assessment scenario and the refined exposure assessment scenarios per population group and survey: mean and 95th percentile (mg/kg bw per day)**

**Appendix E – Main food categories contributing to exposure to propane-1,2-diol esters of fatty acids (E 477) using the regulatory maximum level exposure assessment scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)**

Appendix A–E can be found in the online version of this output ('Supporting information' section):